K011338

SEP 1 3 2001

510(k) Summary

1. Submitter/ Contact Person / Date:

OtoTech, Inc.
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Washington, DC 20006
Telephone: 202-223-0157
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Contact Person: Michael G. Farrow, Ph.D.
510(k) Summary Preparation Date: May 2, 2001

2. Device Names:

Proprietary	OTO-CEM™
Common	Glass Ionomer Bone Cement
Classification	Cement, Bone, Glass Ionomer

3. Predicate: SerenoCem™
Corinthian Medical, Ltd.
Strelley Hall, Strelley Village
Nottingham, Nottinghamshire, NG8 6PE
England
510(k) Number K 003567, February 12, 2001

4. Description of OTO-CEM™

Composition: OTO-CEM™ is a two-component system consisting of a glass powder and polyalkenoic acid (free of monomers). By mixing the two components, a viscous moldable ionomeric cement is obtained which hardens *in situ.*

Physical and Chemical Properties: Setting is based on a neutralization of the basic silicate powder with the aqueous polyalkenoic acid; the reaction temperature remains in the physiological range.

During the time of setting, OTO-CEM™ is sensitive to water. In this phase, contact with liquids like blood, phpysiological rinsing solutions, and body fluids must be avoided. Excessive moisture contamination inhibits complete hardening. Only in such case OTO-CEM™ forms a soft, ion releasing (toxic) gel and loses its adhesive properties.

After complete curing, OTO-CEM™ has to be protected against desiccation. Desiccation may occur on the surface after a few minutes if it is not protected and leads to fine, superficial cracks and reduced mechanical properties.

After proper curing, OTO-CEM is a biocompatible, hydrophilic system. This property allows the cement to "flow" onto the abone. Once the cement is in contact with bone, the carboxylate groups of the polymeric chains create a stable bond to the Ca ions.

5. Indication for Use:

   OTO-CEM™ is indicated "for use in otological surgery for reconstruction of the ossicular chain". Compared to the predicate, SerenoCem™, the safety and effectiveness, if user instructions are strictly adhered to, is substantially equivalent.

6. Technological Characteristics compared to Predicate

   Both OTO-CEM™ and the predicate, SerenoCem™ utilize the same types of materials and mode of action, viz, an inorganic glass powder reacted with an organic polyacid. In both cases, the setting does not produce thermal damage to tissue. Both OTO-CEM™ and the predicate have similar packaging and preparation.

7. Performance data

   Preclinical and clinical applications of this cement have shown it to be safe and effective if used as labeled. It has been shown to be biocompatabile in laboratory

8. Table of Comparison with the Predicate

Similarities

OTO-CEM™	**SerenoCem™ (K 003567)**
Indication for use: For use in otological surgery for reconstruction of the ossicular Chain	Indication for use: For use in otological surgery for reconstruction of the ossicular chain
Bioactive	Bioactive
Biocompatible	Biocompatible
Bonds to bone and metal	Bonds to bone and metal
Osteoconductive	Osteoconductive
Hybrid glass polymer composite	Hybrid glass polymer composite
Alkaline inorganic glass reacted with polyacid	Alkaline inorganic glass reacted with polyacid
Non-exothermic	Non-exothermic
Reaction does not generate heat	Reaction does not generate heat
No appreciable shrinkage	No appreciable shrinkage
For non-weight bearing applications	For non-weight bearing applications
No pigments	No pigments
Single Use Device	Single Use Device

Stability in Patient: about 50 years	Stability in Patient: about 50 years
User: Certified Otologic Surgeon	User: Certified Otologic Surgeon
MRI compatible	MRI compatible
Safe in Microwave	Safe in Microwave
No interaction with drugs observed	No interacting with drugs observed
Sterilization via gamma irradiation	Sterilization via gamma irradiation
Resterilization not permitted	Resterilization not permitted
Accessories include applicator & 110v mixer.	Accessories include applicator & 110v mixer

Differences

No bactericidal properties claimed	Bactericidal properties
Tower DualPeel® self seal pouch	Double foil package around capsule.
Contents of pouch: one gram / capsule	Contents of package: 0.75 / capsule
Store at 18-21 degrees centigrade	Store at 15-23 degrees centigrade

Contraindications

OTO-CEM™, in a non-solid format, must not be placed 1) in direct contact with cerebral and nerve tissue, with cerebral spinal fluids and inner ear fluid; Use of OTO-CEM™ in CNS surgeries has been associated with risk of mortality; 2) directly on the dura mater; 3) for treatment and closure of soft tissue and and cartilage defects; 4) in cases in which a post-operative radiotherapy of the implantation site or the adjacent area cannot be excluded; 5) with known hypersensitive reactions against one or more components of polymaleinate ionomer; 6) in cases of severe systemic diseases especially with renal insufficiencies).

Side Effects: Until now, the following side effects / events have been observed: in a few cases, reversible seroma; occasional rejection. If the aforementioned contraindication 1) and 2) Are ignored, neurological reactions resulting in death may occur.

Technical Effects: Any mixing with other materials (i.e., fibrine glue) is not permitted. OTO-CEM™ after hardening, bonds strongly to metal instruments and should be rinsed off with cold water before setting is completed.

SerenoCem™ materials must not be placed whilst in a nonsolid format directly in contact with peripheral nerves, cranial nerves, neural tissue, or in contact with the brain, dura or other parts of the central nervous system. A blockage of nerve conduction, which may not be reversible, may occur. Not suitable for loadbearing applications.

This product must therefore not be Used in Acoustic Neuroma or Skull Based surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 3 2001

OTO-Tech, Inc.
c/o Michael G. Farrow, Ph.D.
Official Correspondent
1901 L St., NW
Suite 250
Washington, DC 20036

Re: K011338
Trade/Device Name: OTO-CEM™
Regulation Number: 21 CFR 872-3275 (b)
Regulatory Class: Class II
Product Code: NEA
Dated: July 11, 2001
Received: July 12, 2001

Dear Dr. Farrow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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INDICATION FOR USE STATEMENT FOR OtoTech, Inc.'s OTO-CEM™

Current indication for Use for OtoTech™, Inc.'s OTO-CEM™ Bone Cement is:

"for use in otological surgery for reconstruction of the ossicular chain"

Prescription Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011338